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10 *Attorneys for Plaintiffs*

11 UNITED STATES DISTRICT COURT
12 FOR THE WESTERN DISTRICT OF WASHINGTON

13 WASHINGTON TOXICS COALITION,)
14 NORTHWEST COALITION FOR)
15 ALTERNATIVES TO PESTICIDES,)
16 PACIFIC COAST FEDERATION OF)
17 FISHERMEN'S ASSOCIATIONS, and)
18 INSTITUTE FOR FISHERIES RESOURCES,)

19 Plaintiffs,

20 v.

21 ENVIRONMENTAL PROTECTION)
22 AGENCY, and MICHAEL O. LEAVITT,)
23 ADMINISTRATOR,)

24 Defendants,

25 AMERICAN CROP PROTECTION)
26 ASSOCIATION, et al.,)

Intervenor-Defendants.)

HONORABLE JOHN C. COUGHENOUR

Civ. No. C01-0132C

REPLY IN SUPPORT OF MOTION FOR
CLARIFICATION THAT THE JANUARY
22, 2004 ORDER'S NOXIOUS WEED
EXCLUSION DOES NOT AUTHORIZE
APPLICATION OF THE COVERED
PESTICIDES DIRECTLY INTO SALMON
SUPPORTING WATERS

NOTED ON MOTION CALENDAR PER
LOCAL RULE 7: JULY 30, 2004

EXPEDITED TREATMENT REQUESTED
DUE TO IMMINENCE OF SPRAYING

REPLY IN SUPPORT OF MOTION FOR CLARIFICATION THAT
THE JANUARY 22, 2004 ORDER'S NOXIOUS WEED EXCLUSION
DOES NOT AUTHORIZE APPLICATION OF THE COVERED
PESTICIDES DIRECTLY INTO SALMON SUPPORTING
WATERS (C01-0132C) - 1-

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1 Plaintiffs Washington Toxics Coalition et al. ("Coalition") hereby submits this reply in
2 support of its request for clarification that the pesticide active ingredients subject to the Court's
3 January 22, 2004 Order cannot be applied directly into salmon supporting waters. The
4 Coalition's motion provides the basis for the requested clarification. This reply addresses
5 discrete arguments made in opposition.

6 First, CropLife accuses the Coalition of previously supporting the authorization of
7 applications of 2,4-D directly into water and now reversing that position. This argument is
8 contrived and entirely contrary to the record. CropLife points to "Plaintiffs' Proposed Pesticide-
9 Specific Exclusions and Alternative Buffers," which was Attachment 1 to its Notice of Filing
10 Proposed Order (Oct. 2, 2003) (Dkt. No. 200). CropLife cites to the column indicating the
11 Coalition's proposal for 2,4-D, which refers to the noxious weed exemption. As CropLife
12 recognizes, that exemption was drawn from National Marine Fisheries Services' biological
13 opinions that did not authorize aquatic applications of 2,4-D or any other pesticide. Moreover,
14 the column adjacent to the one embraced by CropLife provides "Plaintiffs' Rationale" and, for
15 2,4-D, explains: "CropLife has offered no justification for exempting aquatic applications."
16 Throughout the entire document, the Coalition rejected proposals made by CropLife that lacked
17 any justification. In other words, it is plain from this document – the only filing cited by
18 CropLife for its contorted argument that the Coalition supported aquatic applications of 2,4-D –
19 that the Coalition rejected CropLife's proposal to exempt aquatic applications of 2,4-D from the
20 injunction's buffers.

21 The Coalition assures the Court that it never "endorsed" CropLife's proposal to allow
22 aquatic applications directly into water. Instead, it proposed a noxious weed exemption subject
23 to the safeguards routinely imposed by NMFS in its biological opinions. Since NMFS has never

1 authorized the direct application of 2,4-D or any other pesticides directly into salmon supporting
2 waters, the Coalition's proposal cannot fairly be read to endorse such applications, particularly
3 since its noxious weed exemption went no further than NMFS's authorizations.

4 Second, because the oppositions suggest that aquatic applications of 2,4-D are "low risk,"
5 see CropLife Opposition at 5 n.9, the Coalition reminds the Court that 2,4-D is subject to the
6 January 22, 2004 Order because it is used frequently in the Pacific Northwest and the U.S.
7 Geological Survey detected 2,4-D in salmon watersheds at concentrations that exceed aquatic
8 life criteria. See Declaration of Richard Ewing, Ph.D., ¶ 26 (May, 2001). While the
9 Environmental Protection Agency ("EPA") had not completed an ecological risk assessment
10 when the parties briefed the merits on injunctive relief, it released such a risk assessment earlier
11 this year. 69 Fed. Reg. 35,019 (June 23, 2004). That risk assessment concluded that "use of
12 2,4-D for aquatic weed control presents potential risk to aquatic organisms and aquatic plants."
13 Revised Preliminary Risk Assessment for 2,4-D Reregistration Eligibility Decision Document, at
14 2 (May 24, 2004) (available in EPA "E" Docket No. 2004-0167) (Exhibit 1).

15 EPA concluded that estimated environmental concentrations of 2,4-D when used for
16 aquatic weed control would result in exceedances of EPA's levels of concern, including for acute
17 and chronic risk to freshwater fish and invertebrates and for acute risks to aquatic plants. Id. at
18 4. The risk assessment suggests label warnings that include: "This pesticide is toxic to fish and
19 aquatic invertebrates" and "Drift and runoff may be hazardous to aquatic organisms in water
20 adjacent to treated areas." Id. at 11.

21 Third, the Washington State Farm Bureau emphasizes potential adverse impact of
22 invasive aquatic weeds. However, there are alternatives to 2,4-D for aquatic weed control. See
23 <http://www.ecy.wa.gov/programs/wq/plants/leland/control.html>. Indeed, the Washington

1 Department of Ecology did not authorize use of 2,4-D from 1980-2001, see
2 [http://www.ecy.wa.gov/programs/wq/pesticides/final_pesticide_permits/noxious/finalnoxiousfac](http://www.ecy.wa.gov/programs/wq/pesticides/final_pesticide_permits/noxious/finalnoxiousfactsheetfeb3.pdf)
3 [tsheetfeb3.pdf](http://www.ecy.wa.gov/programs/wq/pesticides/final_pesticide_permits/noxious/finalnoxiousfactsheetfeb3.pdf) (at 8), and it authorizes the use of alternative pesticides that are not subject to the
4 January 22, 2004 injunction.
5 [http://www.ecy.wa.gov/programs/wq/pesticides/final_pesticide_permits/noxious/noxiouspermit](http://www.ecy.wa.gov/programs/wq/pesticides/final_pesticide_permits/noxious/noxiouspermitmayfinal.pdf)
6 [mayfinal.pdf](http://www.ecy.wa.gov/programs/wq/pesticides/final_pesticide_permits/noxious/noxiouspermitmayfinal.pdf) (at 9).

7 CONCLUSION

8 For these reasons and those set out in the motion for clarification, the Coalition asks the
9 Court to clarify that the noxious weed exclusion does not authorize applications of any of the
10 covered pesticides directly into salmon supporting waters.

11 Respectfully submitted this 27th day of July 2004.

12
13
14 /s/ Patti Goldman
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EXHIBIT 1

U. S. ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: May 24, 2004
Chemical: 2,4-D
PC Code: 030001, 030004, 030016,
030019, 030025, 030035, 030053, 030063,
030066
DP Barcode: D299136, D286666,
D157261, D231529, D266268, D273173,
D276064, D276251, D276253, D276257,
D276259, D283847, D285506, D286025,
D286666, D286667, D288113, D289413,
D290310

MEMORANDUM

SUBJECT: Environmental Fate and Effects Division Revised Preliminary Risk Assessment for the 2,4-Dichlorophenoxyacetic acid (2,4-D) Reregistration Eligibility Decision Document.

TO: Mark Seaton, Chemical Review Manager
Reregistration Branch II
Special Review and Reregistration Division (7508C)

FROM: Mark Corbin, Environmental Scientist
William Evans, Biologist
James Hetrick, Ph.D., Senior Scientist
Environmental Risk Branch I
Environmental Fate and Effects Division (7507C)

APPROVED

BY: Sid Abel, Branch Chief
Environmental Risk Branch I
Environmental Fate and Effects Division (7507C)

This memo summarizes the attached Environmental Fate and Effects Division (EFED) Revised Environmental Risk Assessment (science chapter) for the 2,4-Dichlorophenoxyacetic acid (2,4-D) Reregistration Eligibility Decision (RED). This document incorporates changes based on error correction comments received from the 2,4-D Task Force dated February 18, 2004. This document includes an assessment of potential risks to aquatic and terrestrial organisms resulting from the use of 2,4-D and its associated chemical forms including 2,4-D dimethylamine salt (2,4-

D DMAS), 2,4-D isopropylamine salt (2,4-D IPA), 2,4-D triisopropanolamine salt (2,4-D TIPa), 2,4-D ethylhexyl ester (2,4-D EHE), 2,4-D butoxyethyl ester (2,4-D BEE), 2,4-D-diethanolamine salt (2,4-D DEA), 2,4-D isopropyl ester (2,4-D IPE) and 2,4-D sodium salt. In this document, the term chemical form is used to refer to the supported technical formulations listed above, while the term formulation refers to the physical nature (e.g. granular or emulsifiable concentrate) of the applied product, and the term end use product is used to refer to any formulated product including mixtures of pesticide sold in the United States.

The 2,4-D Task Force identified a number of registrations which are outdated or inconsistent with respect to the technical labels. EFED has completed modeling as part of this assessment which has relied on maximum single and seasonal application rates derived from the 2,4-D Master Label. In accordance with a memorandum dated March 18, 2003 from the Special Review and Reregistration Division (SRRD), this exposure assessment for 2,4-D has used maximum application rates derived from the 2,4-D Master Label. The 2,4-D Master Label represents all currently registered technical forms of 2,4-D and all data submitted in support of 2,4-D (including esters and salts) has been created at these rates. It is an underlying assumption of this exposure assessment that any labels for formulated products which exceed these maximum application rates will be revised to comply with the Master Label. Use of rates from currently registered end use products which exceed those of the 2,4-D Master Label would result in higher predicted exposures and hence greater potential risk.

2,4-D is an herbicide in the phenoxy or phenoxyacetic acid family that is used postemergence for selective control of broadleaf weeds. 2,4-D, a synthetic auxin herbicide, causes disruption of plant hormone responses. Endogenous auxins are plant hormones. **Upon review and synthesis of this information, EFED concludes use of 2,4-D on terrestrial sites presents the greatest potential risks to: (1) non-target terrestrial plants, (2) mammals, and (3) birds, while the use of 2,4-D for aquatic weed control presents potential risk to aquatic organisms and aquatic plants.** Uses supported for 2,4-D and its chemical forms include terrestrial food crops, terrestrial food and feed crops, terrestrial and greenhouse food crops, terrestrial feed crops, terrestrial non-food crops, terrestrial non-food and outdoor residential uses, aquatic food crops, aquatic non-food outdoor uses, aquatic non-food industrial uses, forestry uses, outdoor residential uses, and indoor non-food uses (see Table 1 in the attached risk assessment for a listing of representative crops). This risk assessment includes suggestions for labeling and identifies gaps and uncertainties resulting from outstanding data requirements.

EFED proposed an environmental fate bridging strategy in the 1988 Registration Standard for the amine salts and esters of phenoxy herbicides and that studies conducted with the acid provide "surrogate data" for 2,4-D amine salts and esters. EFED required submission of data providing information on the dissociation time of 2,4-D amine salts and rate of hydrolysis of 2,4-D esters as confirmatory data for this strategy. There are bridging data for 2,4-D DMAS, 2,4-D IPA, 2,4-D TIPa, 2,4-D EHE, 2,4-D BEE, 2,4-D DEA, 2,4-D IPE and 2,4-D sodium salt. The bridging data indicate esters of 2,4-D are rapidly hydrolyzed in alkaline aquatic environments, soil/water slurries, and moist soils. The 2,4-D amine salts have been shown to dissociate rapidly in water. However, 2,4-D esters may persist under extremely dry soil conditions and sterile acidic aquatic conditions.

The weight of evidence from open-literature and registrant sponsored data reviewed subsequent to establishment of the bridging strategy indicates that 2,4-D amine salts and 2,4-D esters are not persistent under most environmental conditions including those associated with most sustainable agricultural conditions. 2,4-D amine salt dissociation is expected to be instantaneous (< 3 minutes) under most environmental conditions. Although the available data on de-esterification of 2,4-D ester may not support instantaneous conversion from the 2,4-D ester to 2,4-D acid, it does show 2,4-D esters in normal agriculture soil and natural water conditions are short lived compounds with a median half life of 2.9 days. Under these conditions, the environmental exposure from 2,4-D esters and 2,4-D amine salts is expected to be minimal in both terrestrial and aquatic environments. Further analysis is required on reason(s) for 2,4-D BEE persistence in sediments from aquatic field studies. Additionally, the persistence of 2,4-D EHE on foliage and in leaf litter in registrant submitted forest field dissipation studies requires additional investigation. No field dissipation data (terrestrial, forest, or aquatic) have been submitted for the amine salts, 2,4-D IPA, 2,4-D TIPAA, and 2,4-D DEA, or for the esters 2,4-D BEE (aquatic field dissipation data is available for this chemical form) and 2,4-D IPE to determine their persistence under field conditions.

The ecological effects data for the 2,4-D acid and amine salts were pooled and analyzed as a group for fish, aquatic invertebrates, and aquatic plants while the 2,4-D esters were analyzed separately. This decision was based on the fact that the amine salts rapidly dissociate to the acid form of 2,4-D under most conditions and that when the acid and amine salts toxicity values are compared to the aquatic toxicity values of the esters, the toxicity of esters tend to be from two to three orders of magnitude greater. In addition, data indicate that the 2,4-D esters may not hydrolyze rapidly in sterile acidic conditions. For these reasons, the aquatic data for the esters have been pooled and analyzed separately from the acid and amine salts.

For the bird and mammal assessments the toxicity values of the 2,4-D acid, amine salts, and esters were primarily pooled because of the tendency of the amine salts and esters to rapidly convert to the acid form in the terrestrial environment under most conditions. Consideration for pooling data based on toxicity alone was not done because of the limited number of definitive studies on birds. However, for terrestrial plant risk assessments the potential for risk was evaluated separately for the esters and the acid and amine salts since there are distinct differences in the solubilities of the two groups.

Potential risks to aquatic organisms (fish, invertebrates, and plants) and terrestrial organisms (birds, mammals, and plants) are based on modeled estimated environmental concentrations (EEC) and monitoring data. This document also includes a summary of the assessment of potential 2,4-D residues in drinking water based on both monitoring data and modeling. The key findings of the risk assessment discussed below are based on modeling the maximum 2,4-D Master Label rate for all uses.

Key findings of this risk assessment are as follows:

- 2,4-D acid is non-persistent to moderately persistent in aerobic aquatic and terrestrial environments under laboratory and field conditions, is persistent in anaerobic aquatic environments, and is mobile in soil and aquatic environments.

- There were no acute or chronic Level of Concern (LOC) exceedances for aquatic organisms through use of 2,4-D acid and amine salts due to runoff/drift from use on terrestrial sites, no acute LOC exceedances for aquatic organisms due to drift-only of 2,4-D esters to water bodies from use on terrestrial sites, and, there were no acute LOC exceedances for aquatic organisms due to the runoff/drift of 2,4-D esters to water bodies from use on terrestrial sites. Chronic concerns were not evaluated for terrestrial uses of 2,4-D esters.
- Use of 2,4-D acid and amine salts in aquatic weed control through direct subsurface application to water bodies results in an exceedance of the restricted use and endangered species LOCs for freshwater invertebrates. There are no chronic LOC exceedances for this use. Use of 2,4-D BEE in weed control through direct subsurface application to water bodies results in exceedances of the acute risk LOC for freshwater fish and invertebrates and chronic risk LOC for freshwater and estuarine fish and freshwater invertebrates when compared on an acid equivalent basis. Additional characterization of the potential risk associated with the direct application of 2,4-D for aquatic weed control was completed by back-calculating the target concentration needed to reduce EECs below LOCs. This type of consideration provides context to the characterization of potential risk and indicates that for all 2,4-D chemical forms target concentration reduction of up to 10-fold still exceed all LOCs for aquatic organisms.
- Use of 2,4-D acid and amine salts in rice paddies result in exceedances of the acute endangered species LOCs for freshwater invertebrates. The rice model used to predict these EECs is a screening level model which predicts concentration in tailwater at the point of release from the paddy. It is anticipated that once released, the concentration will be reduced and subsequently is expected to decrease away from the point of release. Additional characterization was conducted by considering average application rates (average rates are presented in the quantitative usage analysis dated August 9, 2001 prepared by the Biological and Economic Affairs Division) versus maximum label rates and assuming a proportional reduction in EECs. Consideration of average application rates results in EECs below the endangered species LOC.
- For non-target, aquatic plants, the runoff/drift of 2,4-D acid and amine salts from use on terrestrial crops results in an exceedance of the aquatic vascular plant endangered species LOCs for use of 2,4-D acid and amine salts on pasture and apples. Consideration of average application rates and assuming a proportional reduction in EECs results in EECs below the endangered species LOC.
- For non-target, aquatic plants, there are no LOC exceedances for either the scenario incorporating exposure resulting from the drift of the ester forms to aquatic water bodies or from the runoff of the ester forms to water bodies from use on terrestrial sites.
- The scenario of direct application to water for aquatic weed control for 2,4-D acid and amine salts indicates an acute and endangered species LOC exceedances for aquatic vascular and acute LOC exceedances for non-vascular plants, while the use of 2,4-D BEE

(the only ester registered for aquatic weed control) for direct application to water for weed control results in exceedances of all LOCs for vascular and an acute LOC exceedance for non-vascular plants. Risk to endangered non-vascular plants is not evaluated because at this time there are no listed endangered nonvascular plant species. Additional characterization of potential risk for the direct application of 2,4-D for aquatic weed control was completed by back-calculating the target concentration needed to reduce EEC below LOCs. This type of consideration provides context to the characterization of potential risk and indicates that for all 2,4-D chemical forms target concentration reduction of up to 100-fold still exceed all LOCs for aquatic plants.

- Use of 2,4-D acid and amine salts in rice paddies result in exceedances of the acute and endangered species LOCs for aquatic vascular plants. Consideration of average application rates results in EECs below the endangered species LOCs.
- In general for predicted maximum exposures when compared with oral gavage data there are exceedances of acute LOCs for all use sites except potatoes and citrus for most small birds and some medium birds. There are also exceedances of acute restricted use and endangered species LOCs for medium and large birds feeding on short grass, tall grass, and broadleaf forage/small insects at all use sites except potatoes and citrus. In general, the RQs for predicted mean exposures when compared with oral gavage data will be lower but will still result in multiple restricted use and endangered species LOC exceedances and a few acute LOC exceedances at the higher use rate sites such as non-cropland and asparagus. No definitive endpoint was available for avian acute dietary studies and hence risk was not evaluated using this endpoint. However comparison with the lowest dietary LC_{50} of >5620 mg ae/kg-diet would result in no acute LOC exceedances.
- Avian acute LOCs were exceeded for granular formulations on non-cropland, turf, aquatic ditchbank, aquatic weed control, and cranberries, while banded applications result in exceedances of acute LOCs for all use sites.
- For chronic exposure of birds to non-granular spray, exceedances of chronic LOCs occurred for forage on shortgrass for use of 2,4-D on asparagus, cranberries, forestry, and non-cropland. Consideration of the non-granular spray average application rates results in reduction of chronic risk, but not below LOCs. For banded and granular applications there are exceedances of acute LOCs for most use sites and bird sizes. Consideration of average application rates does not reduce exposure below the LOC for granular and banded applications.
- Acute LOCs for mammals feeding on plants and insects were exceeded for use of non-granular formulations for all uses assessed for small and medium size mammals except potatoes and citrus. There were no exceedances for granivores. Banded applications result in exceedances of acute LOCs at all use sites. Mammalian chronic RQs range from 0.05 to 200 and chronic LOCs were exceeded in all cases with the exception of potatoes and citrus (large insects, seeds). Consideration of average application rates results in EECs below the LOCs for non-granular, granular, or banded applications. However,

consideration of average application rates for non-granular, granular and banded applications did not result in exposure below the chronic LOC.

- Acute LOCs for both non endangered and endangered terrestrial plants were exceeded for non-granular and granular uses at many use sites. Consideration of average application rates did not result in exposure below LOCs.
- Overall, the Agency's level of concern for endangered and threatened freshwater fish and invertebrates, estuarine invertebrates, birds, mammals, aquatic vascular plants, and terrestrial non-target plants is exceeded at many sites for the use of 2,4-D. There are currently no listed endangered estuarine invertebrates or non-vascular aquatic plants.
- EFED conducted an evaluation of the concentrations of 2,4-D to which humans potentially may be exposed through ingestion of drinking water and included modeling and an evaluation of surface water and groundwater monitoring data. A number of modeling approaches were used to provide EECs for drinking water. The highest exposure scenario is the direct application of 2,4-D to surface water bodies for the control of aquatic weeds with an EEC of **4000 microgram acid equivalent per liter (ug ae/l)** for peak (acute) exposure and **627 ug ae/l** for the annual mean (chronic) exposure. Additional modeling was conducted which resulted in lower predicted EECs including a second direct application scenario using an advection/dispersion equation with a setback distance of 1500 feet which predicted an acute EEC of **811 ug ae/l** and a chronic EEC of **102 ug ae/l**, a rice model which predicted an EEC of **1431 ug ae/l**, and PRZM/EXAMS modeling of terrestrial uses which predicts acute EECs between **118 ug ae/l** and **6.9 ug ae/l** and chronic EECs between **9.0 ug ae/l** and **1.0 ug ae/l**. 2,4-D is regulated under the Safe Drinking Water Act (SDWA) and has a Maximum Contaminant Level (MCL) of **70 ug ae/l**, a One-Day Health Advisory (HA) for children of **1000 ug ae/l**, and a Ten-Day HA for children of **300 ug ae/l**. Maximum concentrations of 2,4-D in the monitoring data reviewed were **58 ug ae/l** in finished drinking water from the National Contaminant Occurrence Database (NCOD) and **14.8 ug ae/l** from United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) Program. The highest median 2,4-D concentration of **1.18 ug ae/l** was derived from finished water samples in the NCOD database. The highest time weighted annual mean (TWAM) concentration was **1.45 ug ae/l** from the NAWQA data. Although of high quality, EFED deemed monitoring data non-targeted to 2,4-D use. However, the data provide context to model results and indicate that there is little evidence that concentrations are likely to be found exceeding these standards.
- Dioxin congeners have been identified as a by-product in the production of 2,4-D and its various chemical forms and has been detected in the technical formulations. The potential ecological impact of dioxin in 2,4-D will be addressed in a separate document.

As part of the risk assessment process, EFED characterized the potential risks by evaluating the effect of uncertainties and assumptions used in the risk assessment process which may impact the interpretation of the risk conclusions based on maximum application rates. In general, the characterization can be categorized by those uncertainties and assumptions which may result in

an overestimation of risk, those which may result in an underestimation of risk, and those in which the effect of the uncertainty and assumption cannot be determined. Examples of some of the characterization presented include an evaluation of the effect of modeling assumptions on EECs, the effect of pooling toxicity data, and the effect of evaluating application rates other than maximum label rates. It should be pointed out that these characterizations, though pointing to a general effect of overestimating or underestimating risk, have not resulted in quantifiable changes in the risk conclusions but are merely presented to provide context to the conclusions. There are exceptions where a quantitative characterization was completed, including a comparison of risk from major and minor uses and a comparison of risk when evaluating application rates other than label maximums. However, quantitative bracketing of RQs is not meant as a refinement of the risk conclusions because maximum application rates may still be used. These comparisons are presented to provide context and confidence for the risk conclusions described below and are not meant to imply mitigation recommendations.

As part of the characterization of potential risk associated with 2,4-D use EFED evaluated the effect of major versus minor uses. For 2,4-D, the maximum labeled rates used in this risk assessment are representative of major as well as minor uses. This type of analysis is important because if it were determined that the majority of potential risk for 2,4-D was due to use on minor crops this would suggest that the risk concern is localized and possibly point to mitigation focused on the local use. For this risk assessment, modeling the use of 2,4-D on pasture/rangeland resulted in exceedances of several LOCs. The Quantitative Use Analysis (QUA) report prepared by BEAD indicates that pasture/rangeland is the top use site for 2,4-D at 24% of total use with maximum label rate of 4.0 lbs/acre. Therefore, because pasture/rangeland is a major 2,4-D use over a widespread geographic area and results in potential risks to multiple organisms it is believed that further characterization comparing potential risks for major and minor uses was unnecessary.

Additional characterization of the potential risk from 2,4-D was completed for most modeled uses comparing maximum label rates with average application rates as reported by BEAD. For most terrestrial organisms, LOCs were still exceeded at these lower rates, although RQs were not as high. For aquatic organisms (fish, invertebrates, and plants), maximum labeled rates for specific cropping scenarios were used for the assessment. This type of characterization suggests that for most modeled scenarios (except direct application to water for aquatic weed control) there are no LOC exceedances for aquatic organisms when using average (typical) application rates. Overall, considering average application rates provides context to the characterization of potential risk, however, exceedances will still occur at average rates for both major and minor uses on **non-target terrestrial plants, small mammals, and birds**. The impact of 2,4-D use on non-target plants is expected because 2,4-D is a herbicide.

Characterization of the potential risks due to the direct application of 2,4-D for aquatic weed control was completed by back-calculating the target concentration needed to reduce RQs below LOCs. This type of consideration provides additional characterization of the potential risk associated with 2,4-D and indicates that for all 2,4-D chemical forms the target concentration would need to be reduced nearly ten-fold to reduce exceedances below all LOCs to fish and invertebrates and by nearly a factor of 100 to eliminate all LOC exceedances for aquatic plants. It should also be noted that data from registrant submitted field dissipation studies indicate that

concentrations as high as 13000 ug/l have been detected in individual samples and therefore, estimates of risk based on the target concentration of 4000 ug/l should be tempered by the fact that higher exposures are possible with an associated higher RQ.

The mammalian chronic risk assessment utilized a toxicity endpoint from a rat two-generation reproduction test (NOAEL for growth rate reductions in F1b offspring which the Agency considers as a potentially important effect with implications for the survivability of offspring and therefore a potential impact on fecundity). Because the endpoint is the no effect level for this measured parameter, evaluations of the significance of any exposure excursions above this endpoint were conducted. From these comparisons it can be seen that daily oral dose estimates for wild mammals are sufficiently high to exceed toxicity endpoints ranging from fetal growth reduction to skeletal malformations. Moreover, the analysis suggests that daily exposure estimates for wild mammals are sufficiently high to exceed effects thresholds for developmental effects tested over very short durations of exposure.

Data Gaps

Environmental Fate: The environmental fate database is essentially complete. However several studies have been classified as supplemental. The following studies will assist in fully evaluating the potential risks associated with 2,4-D:

- A single aquatic field dissipation study (164-2) conducted on three separate ponds was submitted for 2,4-D BEE. All three ponds used in this study were alkaline (pH ranged from 7.9 to 8.1). As noted in the environmental fate assessment, the esters of 2,4-D convert to 2,4-D acid by microbially mediated, alkaline catalyzed hydrolysis, however, the rate at which hydrolysis occurs is pH dependent. 2,4-D BEE (as well as 2,4-D DMAS) is likely to be used under alkaline as well as neutral and acidic conditions. In addition, 2,4-D BEE was shown to persist in sediment in this study, however, it is unclear if this is due to slow release from the granular formulation or due to persistence. EFED believes that the studies on 2,4-D BEE do not represent the complete range of conditions under which 2,4-D BEE is likely to be used and do not provide data to fully understand the reason for the persistence of 2,4-D BEE in sediment. Therefore, EFED believes that additional data on the behavior of 2,4-D BEE under acidic to neutral aquatic conditions in a water/sediment system will aid in fully evaluating the aquatic use of 2,4-D BEE.
- A laboratory volatility study (163-2) for 2,4-D IPE was classified as unacceptable. A laboratory volatility study for 2,4-D IPE is necessary to assess the volatility of this ester.
- Terrestrial field dissipation studies (164-1) were required by SRRD in 1995 for 2,4-D IPA, 2,4-D TIPA, and 2,4-D DEA but have not been submitted. These studies will aid in fully assessing the behavior of these chemical forms under actual use conditions. The requirement was reserved for 2,4-D BEE and 2,4-D IPE. EFED believes a terrestrial field dissipation study for 2,4-D BEE will aid in fully assessing the behavior of this chemical form under actual use conditions. 2,4-D IPE is currently registered only as a growth inhibitor and therefore EFED does not believe a terrestrial field dissipation study is needed for this chemical form.
- Aquatic field dissipation studies (164-2) in a rice use scenario for 2,4-D IPA, 2,4-D TIPA, and 2,4-D DEA will aid in fully assessing the behavior of these chemical forms

under actual use conditions.

- Aquatic field dissipation studies (164-2) in an aquatic weed control scenario were required by SRRD in 1995 for 2,4-D IPA, 2,4-D TIPA, and 2,4-D DEA but have not been submitted. These studies will aid in fully assessing the behavior of these chemical forms under actual use conditions.
- Forest field dissipation studies (164-3) were required by SRRD in 1995 for 2,4-D IPA, 2,4-D TIPA, and 2,4-D DEA but have not been submitted. These studies will aid in fully assessing the behavior of these chemical forms under actual use conditions. The requirement was reserved for 2,4-D BEE, however, EFED believes a forest field dissipation study for 2,4-D BEE will aid in fully assessing the behavior of this chemical form under actual use conditions. 2,4-D IPE is not used in forestry applications and is therefore not needed at this time.

Ecological Effects: The ecological toxicity data base is fairly complete with the exception of the terrestrial plant testing on the typical end-use product (TEP). In addition to plant testing with TEP the following studies will assist in fully evaluating the potential risks associated with 2,4-D:

- Estuarine Fish - Since environmental fate data suggest that 2,4-D esters may persist under certain conditions and RQs associated with freshwater fish indicate potential risk to fish for 2,4-D BEE, further acute testing with 2,4-D BEE will aid in fully assessing the toxicity of this ester.
- Estuarine/marine invertebrates, acute - Since environmental fate data indicate that 2,4-D esters may persist under certain conditions and RQs associated with freshwater invertebrates indicate potential risk to aquatic invertebrates for 2,4-D BEE, further acute testing with 2,4-D BEE will aid in fully assessing the toxicity of this ester.
- Estuarine and Marine Invertebrate, Chronic - Since freshwater chronic risk quotients are exceeded for 2,4-D BEE (13.05), a chronic study will aid in fully assessing the risks associated with 2,4-D BEE for marine invertebrates
- Sediment toxicity testing - Due to the persistence and high toxicity of the 2,4-D BEE granular formulation when used in a direct application to water a sediment toxicity test following EPA guidelines is requested on the granular formulation.
- Non-Target Terrestrial Plants - Currently, no studies following the EPA protocols are available for the 2,4-D sodium salt, and some data is missing or unavailable for some of the other active ingredients. Current EFED policy requires testing of the TEP because these products sometimes include surfactants or adjuvants to increase the absorption to the foliage and may increase the toxicity of the product. Toxicity testing at the same rates as the technical grades using the TEP for the sodium salt and other active ingredients for which EPA currently does not have data would likely show higher toxicity. Since EFED has pooled the data for terrestrial plants for the acid and amine salts separately from the esters, EFED is only requesting TEP representative testing from the acid and amine salts group, and representative testing from the ester group. Factors which might affect the selection of the TEPs include the product which represents the largest use based on total poundage, the largest number of acreage treated, and/or the toxicity level of the product. The test products should include the most common and most active surfactants and adjuvants which might affect the toxicity of the product. The 2,4-D Task Force may want to confer with the Agency before finalizing which products

they prefer to test.

Suggested Label Language

Based on the mobility and moderate persistence under actual use conditions the following Groundwater Advisory statement should be added to the 2,4-D Master Label.

“This chemical has properties and characteristics associated with chemicals detected in groundwater. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination. Application around a cistern or well may result in contamination of drinking water or groundwater.”

The labels for the aquatic use of 2,4-D for weed control are inconsistent. The labels indicates that 2,4-D should be applied at a rate to reach a target concentration of 4000 ug ae/l. However, label language indicates that if analysis of water from water bodies used as drinking water sources exceeds the MCL of 70 ug ae/l the source should not be used as potable water. This language should be clarified to provide clear guidance to users of 2,4-D in water bodies supplying drinking water regarding how to balance the need for aquatic weed control while maintaining 2,4-D levels below appropriate health based standards. Suggested language is as follows:

*“This pesticide is regulated under the Safe Drinking Water Act (SDWA) which has established a maximum contaminant limit (MCL) in drinking water of 70 ug ae/l for 2,4-D. Waters treated with 2,4-D should not be used for potable water if laboratory analysis indicates concentrations greater than **70 ug ae/l** remain present in the water. The applicator of this pesticide to water bodies for aquatic weed control should consult with the operator of the drinking water intake prior to treatment to insure that an appropriate sampling schedule is in place to determine if exceedances occur. Also, the applicator should consult with the agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is needed.”*

For aquatic weed control in water bodies not used for potable water, the registrant indicates that 2,4-D will not be applied to an entire water body due to concerns related to oxygen depletion and a corresponding loss of aquatic wildlife. It has been stated that a typical application would involve applying 2,4-D to no more than one-half of a water body at any given application. Therefore, EFED suggests the following label language to address this:

“Treatment of aquatic weeds can result in oxygen loss from decomposition of dead weeds. This loss can cause fish suffocation. Therefore, to minimize this hazard, treat no more than one-third to one-half of the water in a single operation and wait at least 10 to 14 days between treatments. Begin treatment along the shore and proceed outwards in bands to allow fish to move into untreated areas. Consult with the State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is needed.”

The 2,4-D Master label for aquatic weed control indicates that the setback distance for surface applied weed control may change depending on the results of dispersion studies. **This language**

should be removed from the Master Label.

The 2,4-D Master Label indicates that for the treatment of submerged aquatic weeds a setback of 1500 feet from drinking water intakes should be observed. However, members of the 2,4-D Task Force have indicated in meetings that this distance may change. The setback distance must be set at a fixed distance in consultation with the Agency. **EFED recommends a setback distance be established for the 2,4-D Master Label and all end use products which is protective of human health.**

In addition, EFED recommends that the following language be included on the appropriate labels:

Environmental Hazards

Manufacturing Use:

“This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment washwaters.”

End Use Products:

“This pesticide may be toxic to fish and invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark **except as noted on appropriate labels**. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment wash waters or rinsate. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment washwaters or rinsate.”

Statement to minimize the potential for surface water contamination for all non-granular end-use products:

“This product may contaminate water through drift of spray in wind. This product has a potential for runoff for several days to weeks after application. Poorly draining soil with shallow water tables are more prone to produce runoff that contains this product. A level, well maintained vegetative (grass) buffer strip between areas to which this product is applied and the surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours. Sound erosion control practices will reduce this product’s contribution to surface water contamination.”

Although not required, if the product is used by homeowners and/or farmers the following

statement can be added for emphasis. Use of the label suggested label language is encouraged if the risk assessor and risk manager are confident that without prudent warnings there is a greater likelihood of effects. These statements will assist end-users in creating effective buffer strips.

Targeted User Community:

1. **Homeowner's Label [Consumer]** - Avoid applying this product to ditches, swales, and drainage ways. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.
2. **Farmer's Label [Commercial]** - A level, well maintained vegetative (grass) buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall- runoff (See manual at the following Internet address:
<http://www.nrcs.usda.gov/water/quality/common/pestmgt/files/core4.html>).
Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours."

Spray Drift Management

Drift is transport of pesticides through air away from the target site and includes spray drift and volatilization. Spray drift, the movement of pesticide droplets off-target during or shortly after application, has been well studied and is not dependent on the properties of the active ingredient. Short range spray drift transport and resulting exposures to non-target organisms is quantified in EFED risk assessments. Currently, when specific label instructions are not available, EFED accounts for spray drift in both drinking water and ecological exposure assessments with the use of default assumptions for the percentage of drift deposition based on application method. EFED has established default spray drift percentages for pesticides regardless of chemical properties for aerial application, ground application, and orchard airblast.

Default values for drinking water exposure scenarios are 16%, 6.4%, and 6.3% of the application rate for aerial, ground boom and airblast applications, respectively. The default values for the drinking water exposure were generated using AgDRIFT version 1.03 which uses a semi-mechanistic model (AGDISP) for aerial applications and is based on empirical data set (Spray Drift Task Force data) for ground boom and airblast applications. The derivation of the spray drift loading values is described in Appendix B of the Guidance for Use of the Index Reservoir in Drinking Water Exposure Assessments and are based on the following application and wind speed assumptions:

For ground boom applications

- nozzle height no more than 4 feet above the ground or crop canopy
- wind speed is 10 mph or less at the application site and,
- **medium or coarser** spray according to ASAE 572 definition for standard nozzles.

For aerial applications

- boom width less than 75% of the wingspan or 90% of the rotary blade,

- use of upwind swath displacement,
- wind speed 3 - 10 mph, and
- use medium or coarser spray according to ASAE 572 definition for standard nozzles.

For orchard/vineyard airblast applications

- spray is not directed above trees/vines,
- outward pointing nozzles are shut off at row ends and outer rows, and
- wind speed is 3 -10 mph at the application site as measured by an anemometer outside of the orchard/vineyard on the upwind side.

Default values for ecological exposure scenarios are 5% for aerial applications and 1% for ground applications, with no set value for orchard airblast, in ecological exposure assessments. For the ecological assessment, the default values of 5% for aerial applications and 1% for ground applications were established based on open literature and research prior to establishment of the Spray Drift Task Force and were therefore not generated using AgDRIFT. Testing of the default spray drift values for ecological assessments using AgDRIFT provides context for the default assumptions. Analysis of the 1% ground application drift percentage using AgDRIFT (with the same assumptions as for drinking water outlined above) indicates that the default value likely underestimates drift from single events under relatively high drift conditions. A similar underestimation likely occurs for the 5% aerial drift value.

For 2,4-D, the EECs predicted for drinking water and ecological assessments are based on the assumptions of drift outlined above for ground and aerial applications. Variance from these assumptions will result in differences in predicted concentrations. For the ecological assessment, as with the drinking water assessment, variance from the assumptions behind these default values could result in increased risk. In general, a decrease in droplet size or increase in wind speed at the time of application will result in higher predicted EECs and risk to non-target organisms. Alternatively, if droplet size is more coarse or wind speeds are lower, exposures due to drift would be lower.

Transport resulting from volatilization is highly dependent on the properties of the active ingredient (e.g Henry's Law constant) and as well as a number of environmental parameters. The magnitude and impact of potential transport of 2,4-D acid, salts and esters via volatilization or long range drift away from the target site cannot be quantified and is an uncertainty in this assessment.

Endangered Species Statement

As an herbicide, 2,4-D has the potential to affect federally listed threatened and endangered vascular plants. Until additional data are submitted and a determination made whether a species specific assessment needs to be conducted for listed plants, the mitigation strategy articulated in the RED will serve as interim protection to reduce the likelihood that listed species will be exposed to 2,4-D.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species,

and to implement mitigation measures that address these impacts. EPA is not requiring specific label language at the present time relative to threatened and endangered species. The general risk mitigation required through this RED will serve to protect listed species of potential concern until such time as the agency refines its risk assessment for plants and acute/chronic effects to mammals, birds, and aquatic organisms. If in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

Peer Reviewers

This chapter was peer-reviewed by Pat Jennings, Risk Assessment Process Leader (RAPL), Norm Birchfield, Senior Biologist, and Ed Odenkirchen, Senior Biologist.